REMARKS

Claims 23-39 and 68-94 are pending in this application. Claims 25, 26, 28, 35, 36, 69-71, 73-75, 77-79, and 85-94 have been withdrawn from consideration as being directed to a non-elected species. Claims 23, 24, 27, 29-34, 37-39, 68, 72, 76, and 80-84 were variously rejected under 35 U.S.C. §112, first paragraph. Claims 24, 27, 29-34, 37-39, 68, 72, 76 and 81-84 were variously rejected under 35 U.S.C. §112, second paragraph. Claims 23, 24, 27, 29-31, 33, 34, 37-39 and 80-82 were variously rejected under 35 U.S.C. §102. Claims 1-16, 23, 24, 33, 34 and 82 are variously rejected under the judicially created doctrine of obviousness-type double patenting.

By this amendment, claims 30, 81, and 83 have been canceled, claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, and 80 have been amended, and new claims 95-97 have been added, without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments and new claims can be found, *inter alia*, throughout the specification and the claims as originally filed. For example, support for the amendment to claims 23, 33, 76 can be found, *inter alia*, at page 12, lines 13-15, and in the Abstract where it is disclosed that the amylin or amylin agonist may be administered "alone or in conjunction with another obesity relief agent." Support for the amendment to claim 32 is found, for examples, at page 29, lines 9-11. Support for new claims 95-97 can be found, for example, at page 35, lines 24-27.

The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Although claims 25, 26, 28, 35, 36, 69-71, 73-75, 77-79, and 85-94 have been withdrawn from consideration as being directed to a non-elected species, Applicants note that, upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under Obviousness-type Double Patenting

Claims 23, 24, 27, 29-34, 37-39, 68, 72, 76, and 80-84 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-16 of co-pending U.S. Pat. Application No. 09/870,762 (hereinafter "the '762 application"). Claims 33, 34 and 82 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 64 and 68 of U.S. Pat. No. 6,956,026 (hereinafter "the '026 patent"). Claims 33 and 82 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 6 of U.S. Pat. Application No. 10/851,574 (hereinafter "the '574 application"). Claims 23, 24, 33 and 34 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 34 and 35 of U.S. Pat. No. 5,686,411 (hereinafter "the '411 patent") as evidenced by Tsanev (*Vutr. Boles* 23:12-17, 1984, abstract). Claims 23 and 33 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 11 and 13 of U.S. Pat. No. 5,321,008 (hereinafter "the '008 patent") as evidenced by Tsanev and U.S. Pat. No. 5,739,106.

As amended herein, the claimed invention is directed to methods of treating obesity in a human subject through administration of a composition containing an amylin or an amylin agonist and the composition is not administered in conjunction with another obesity relief agent. The methods are directed to treating obesity in a human subject in need of such treatment and the amount of the composition administered is effective to treat obesity.

The '762 and '574 applications

With regard to the provisional rejections, Applicants are willing to consider submitting a terminal disclaimer in the present application with regard to the '762 application and the '574 application should these applications issue as a patent prior to the present application.

The '026 patent

Applicants respectfully traverse this rejection of pending claims 33, 34 and 82 over claims 64 and 68 of the '026 patent.

Relevant to the pending claims, claim 64 of the '026 patent is directed to a method of reducing food intake in a subject comprising administering exendin-4 and an amylin agonist and claim 68 of the '026 patent is directed to a method for reducing appetite in a subject comprising administering exendin-4 and an amylin agonist. The '026 patent demonstrates that administration of exendin-4 alone inhibits food intake. See, for example, Examples 1-4 of the '026 patent.

As noted above, claims 33, 34, and 82 are directed to methods of treating obesity through administering a composition containing an amylin or an amylin agonist, where the composition is not administered in conjunction with another obesity relief agent. Since the cited claims of the '026 patent are directed to the administration of both exendin-4 and an amylin agonist, the cited claims do not teach or suggest the claimed invention. Thus, claims 64 and 68 of the '026 patent do not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '411 patent

Applicants respectfully traverse this rejection of pending claims 23, 24, 33, and 34 over claims 34 and 35 of the '411 patent.

Claims 34 and 35 of the '411 patent are directed to methods for the treatment of diabetes mellitus in a mammal comprising the administration to said mammal of a therapeutically effective amount of a particular amylin agonist analogue.

As noted above, claims 23, 24, 33, and 34 are directed to methods of treating obesity in a human subject in need of such treatment through administration of a composition containing an amylin or an amylin agonist, including an amylin agonist analogue. The amount of the composition administered is effective to treat obesity.

The cited claims of the '411 patent are silent with regard to treating obesity. Although obesity is a common among those with diabetes, a claim to treating diabetes mellitus with an amylin agonist analogue does not necessarily teach or suggest treating patients with obesity as

claimed. Further, nothing in the cited claims teaches or suggests the use of an amylin or an amylin agonist in an amount effective to treat obesity. Since the cited claims do not teach or suggest treating obesity or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims. Thus, claims 34 and 35 of the '411 patent do not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '008 patent

Applicants respectfully traverse this rejection of pending claims 23 and 33 over claims 11 and 13 of the '008 patent.

Claim 11 of the '008 patent are directed to a method for the treatment of diabetes mellitus in an insulin-requiring mammal comprising administering to the mammal a therapeutically effective amount of a calcitonin, where the mammal is a human. Claim 13 of the '008 patent is directed to the method of treatment of type II diabetes mellitus comprising the step of administering a therapeutically effective amount of an insulin and a calcitonin where the ratio of insulin to calcitonin from about 100:1 to about 1:2 and is effective to achieve improved glycemic control over insulin therapy alone.

As noted above, claims 23 and 33 are directed to methods of treating obesity in a human subject in need of such treatment through administration of a composition containing an amylin or an amylin agonist. The amount of the composition administered is effective to treat obesity.

The cited claims of the '008 patent are silent with regard to treating obesity. Although obesity is a common among those with diabetes, a claim to treating diabetes mellitus does not necessarily teach or suggest treating patients with obesity as claimed. Further, nothing in the cited claims indicates the use of an amylin or an amylin agonist in an amount effective to treat obesity. Since the cited claims do not teach or suggest treating obesity or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims. Thus, claims 11 and 13 of the '008 patent do not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

In sum, Applicants submit that the pending claims are patentably distinct from the cited claims in the cited patents. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under the judicially created doctrine of obviousness-type double patenting.

Rejections under 35 U.S.C. §112, first paragraph

Claims 23, 24, 27, 29-34, 37-39, 68, 72, 76, and 80-84 were variously rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the new matter and enablement requirements.

New Matter

Claims 23, 24, 27, 29-34, 37-39, 68, 72, 76, and 80-84 were variously rejected as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims were rejected as allegedly failing to comply with the written description requirement regarding new matter. Applicants respectfully traverse these rejections and maintain the reasons for traverse already of record. Applicants also maintain that support for the amylin or amylin agonist amounts recited in claims 30, 81, and 83 is found in the specification at page 27, lines 17-26, and page 28, lines 1-10, as described in the Supplemental Amendment filed November 19, 2004.

Although Applicants disagree with these new matter rejections, the claims have herein been amended in order to facilitate disposition of the present case. Accordingly, the pending claims are fully described in the specification as filed and Applicants respectfully request reconsideration and withdrawal of the new matter rejections.

Enablement

Claims 68, 72, 76, 83 and 84 were rejected for allegedly not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse this rejection.

The Examiner asserts that the specification does not enable the claimed methods comprising administering any peptide or amylin agonist analogue comprising the amino acid

sequence of SEQ ID NO:14. Final Office Action, section 35, page 16. Applicants respectfully disagree with this assertion.

Amylin agonist analogues comprising SEQ ID NO: 14 for use in the present invention are described in the specification and well known in the art. For example, page 40, 41, and 46 of the specification provide representative examples of amylin agonist analogues comprising SEQ ID NO: 14 for use in the claimed invention. Amylin agonist analogues comprising SEQ ID NO: 14 were also known in the art at the time the present application was filed. For example, such amylin analogues include those described in U.S. Pat. No. 5,686,411, as described in the present specification at page 13, lines 23-28, and those described in U.S. Pat. No. 6,114,304, of record. These amylin agonist analogues have been shown to mimic an effect of amylin *in vitro* or *in vivo*. For example, as shown in Examples 7-9 of the present specification, many of these amylin agonist analogues possess amylin activity (receptor binding or muscle assay) comparable to that of human amylin and to that of ^{25,28,29}Pro-h-amylin, pramlintide.

In addition, conventional assays for identifying amylin agonist analogues and for detecting amylin activity of compounds comprising SEQ ID NO: 14 are described in the specification and known in the art. For example, the specification at page 19, line 6, to page 24, line 15, describes how to make amylin analogues and how to assess the compounds for amylin activity. U.S. Pat. Nos. 5,686,411 and 6,114,304 also provide such information. Examples 1-3 of the specification describe how to assess the compounds for activity in treating obesity.

In support of this rejection, the Examiner states that "the art in general reflects sensitivity of proteins, polypeptides, or peptides, to alteration of even a single amino acid residue in their amino acid sequence" and then cites two examples of proteins that are sensitive to an amino acid change at a particular site. Final Office Action, pages 18-19.

The amylin agonist analogue of SEQ ID NO:14 does not permit any and all amino acid substitutions at any and all amino acid positions of amylin. The amino acid substitutions defined in SEQ ID NO: 14 are limited to only specific amino acid substitutions at only particular amino acid positions of amylin. As noted above, the specification demonstrates that many species of amylin analogues that fall within the genus of SEQ ID NO:14 have activities comparable to native amylin and to pramlintide.

Applicants respectfully note that the test for enablement is not whether a certain amount of experimentation is required to practice an invention, but rather whether the amount of experimentation is "undue." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). "Since one embodiment is ... disclosed in the specification, along with the general manner in which its current range was ascertained, ... other permutations of the invention could be practiced by those skilled in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d. 788, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). Applicants respectfully submit that the specification provides a reasonable amount of guidance to the skilled artisan and that any additional necessary experimentation is presumed to be within the level of ordinary skill in the art.

The specification, including the examples, illustrates the operation of the invention. Amylin analogues according to SEQ ID NO:14 and assays for identifying such amylin analogues with amylin agonist activity are described in the specification and known in the art. Following these teachings, using amylin agonist analogues other than ^{25,28,29}Pro-h-amylin is not seen to involve undue experimentation. Thus, Applicants respectfully submit that the specification adequately teaches the skilled artisan how to make and use, *i.e.*, enables, the claimed invention.

Thus, Applicants respectfully submit that a *prima facie* case of lack of enablement has not been established and the pending claims are in compliance with the enablement requirements. Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

In sum, Applicants submit that the pending claims fall within the subject matter that is described and enabled by the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

Claims 24, 27, 29-34, 37-39, 68, 72, 76 and 81-84 were variously rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §102

Claims 23, 24, 27, 29, 30, 33, 34, 37, 38 and 80-82 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by the '026 patent (U.S. Pat. No. 6,956,026). Claims 23, 24, 29, 30, 33, 34, 37, 38 and 80-82 were rejected under 35 U.S.C.§102(b) as allegedly anticipated by Thompson *et al.* (*Diabetes*, 46 (Suppl. 1):30A, May 1997; hereinafter "Thompson, May 1997"). Claims 23, 24, 29, 30, 31, 33, 34, 37-39 and 80-82 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Thompson *et al.* (*Diabetologia*, 40:1278-1285, November 1997; hereinafter "Thompson, November 1997"). Claims 23, 24, 29-31, 33, 34, 37-39 and 80-82 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kolterman *et al.* (*Diabetologia*, 39:492-499, April 1996; hereinafter "Kolterman (1996)"). Claims 23, 24, 27, 29-31, 33, 34, 37-39 and 80-82 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kolterman *et al.* (WO 96/40220; hereinafter "Kolterman ('220)") as evidenced by Tsanev. Applicants respectfully traverse these rejections.

As amended herein, the claimed invention is directed to methods of treating obesity in a human subject through administration of a composition containing an amylin or an amylin agonist and the composition is not administered in conjunction with another obesity relief agent. The methods are directed to treating obesity in a human subject in need of such treatment.

The '026 patent

The '026 patent describes administration of an exendin or an exendin agonist as an appetite suppressant for reducing weight of a subject. The '026 patent also describes administration of the exendin or exendin agonist in conjunction with an amylin or an amylin agonist. The only mention of an amylin or an amylin agonist in the '026 patent is for

administration along with exendin. See, for example, the '026 patent, column 5, lines 20-31 and lines 53-59, column 13, lines 25-30, and claims 16, 32, 46, 60, and 68. The '026 patent does not teach the use of an amylin or an amylin agonist alone, not in conjunction with another obesity relief agent.

Since the reference does not teach administration of an amylin or an amylin agonist not in conjunction with another obesity relief agent, *i.e.*, alone, the '026 patent does not teach the claimed methods. Thus, the '026 patent does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(e).

Thompson, May 1997

At section 5 on page 3 of the Final Office Action, the Examiner acknowledges that the declaration under 37 C.F.R. §1.131 filed September 2, 2004[1] antedates Thompson, May 1997. However, based on alleged new matter, the Examiner has granted the pending claims the effective filing date of the present application, December 6, 1999.

Applicants respectfully submit that the new matter rejections have been properly addressed herein and the pending claims are entitled to the priority of the filing date of the priority application, June 6, 1997. Thus, since the filed declaration under 37 C.F.R. §1.131 antedates Thompson, May 1997, the rejection based on this reference is moot. Applicants respectfully request withdrawal of this rejection under 35 U.S.C. §102(b).

Thompson, November 1997

The Examiner has granted the pending claims the effective filing date of the present application, December 6, 1999, based on alleged new matter. Applicants respectfully submit that the new matter rejections have been properly addressed herein and the pending claims are entitled to the priority of filing date of the priority application, June 6, 1997. Since this priority date antedates Thompson, November 1997, Applicants respectfully submit that the reference is not a properly cited reference under 35 U.S.C. §102(b) and the rejection based on this reference is moot. Applicants respectfully request withdrawal of this rejection under 35 U.S.C. §102(b).

[1] Applicants note that the declaration under 37 C.F.R. §1.131 addressing Thompson, May 1997 was originally submitted to the Office on December 5, 2002.

Kolterman (1996)

Kolterman (1996) describes the use of an amylin agonist, pramlintide, for treating patients with insulin-dependent diabetes mellitus and demonstrates that administration of the amylin agonist significantly reduces postprandial plasma glucose concentrations. Kolterman (1996) does not teach the use of the amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients administered the amylin agonist. Kolterman (1996) is silent with regard to the effect of the amylin agonist on body weight.

The Examiner states that "Kolterman's (1996) patients who were treated with 30 micrograms of subcutaneously administered pramlintide showed a lower body weight of 70.6 ± 2.7 kg compared to the placebo controls whose body weight was about 4.0 kg higher, i.e., 74.5 ± 2.7 kg (see Table 1)." Final Office Action, section 41, page 26. Applicants respectfully point out that this interpretation of Kolterman (1996) is incorrect.

Table 1 of Kolterman (1996) describes the demographic characteristics of the 84 subjects entering of the study, not completing the study. The subjects are segregated in Table 1 by treatment group to show that the "mean age, weight, duration of diabetes and base-line haemoglobin A_{1C} concentrations were similar for the various groups." See, Kolterman (1996), page 494, paragraph entitled "Demographics." The mean weight listed for the various treatment groups is prior to the 14-day study. Thus, Table 1 does not demonstrate the effect of pramlintide administration on weight loss. Kolterman (1996) does not report the weight of the subjects at the end of the study and nothing in the reference indicates that pramlintide had any effect on the weight of the subjects. Applicants respectfully submit that Kolterman (1996) does not explicitly teach the claimed methods.

In addition, the Examiner asserts that "Kolterman's (1996) method of subcutaneous administration of pramlintide to a Type I diabetic patient necessarily serves as the instantly claimed method of treating obesity and clearly anticipates the instant invention." Final Office Action, section 24, page 8. Applicants disagree with this assertion. The patient population of Kolterman (1996) is not necessarily the same as the claimed subject, *i.e.*, a subject in need of a method of treating obesity. The Examiner has provided no extrinsic evidence to show that these patient populations are one in the same.

Applicants respectfully note that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999); emphasis added.

The courts have held that the phrase "in need thereof" is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003). Thus, Kolterman (1996) cannot render unpatentable by inherency the subject population of the claimed invention.

A reference which teaches treating type I diabetic patients with an amylin or amylin agonist does not necessarily teach treating patient with obesity. Thus, the claimed invention cannot be recognized by one skilled in the art as inherently taught in the cited reference.

Applicants respectfully submit that Kolterman (1996) does not explicitly or inherently teach the claimed methods. Thus, the cited reference does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

Kolterman ('220)

As noted above, the claimed invention is directed to methods of treating obesity in a human subject in need of such treatment through administration of an amylin or an amylin agonist.

Kolterman ('220) describes the use of an amylin agonist for treating type II diabetes mellitus and demonstrates that administration of an amylin agonist significantly reduces postprandial plasma glucose concentrations in patients with type II diabetes mellitus. Kolterman ('220) does not teach the use of an amylin or an amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients administered an amylin or an amylin

agonist. Kolterman ('220) is silent with regard to the effect of an amylin or an amylin agonist on body weight.

This rejection is based on alleged inherent anticipation by Kolterman ('220). The Examiner asserts that the method of Kolterman ('220) is the same as the claimed method "based upon the fact that the method step, the product administered, the amount of the product administered, and the route by which the product is administered, and the human patient population to which the product is administered, are overlapping in the two methods." Final Office Action, page 28. Applicants disagree with this assertion.

An "overlap" in the two methods is not the standard to establish inherent anticipation. Applicants respectfully note that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999); emphasis added.

The courts have held that the phrase "in need thereof" is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003). Thus, Kolterman ('220) cannot render unpatentable by inherency the subject population of the claimed invention.

The patient population of Kolterman ('220) is not necessarily the same as the claimed subject, *i.e.*, a subject in need of a method of treating obesity. Obesity is indeed a common characteristic of patients with type II diabetes mellitus. However, a reference which teaches treating type II diabetic patients with an amylin or amylin agonist does not necessarily teach treating patients with obesity as claimed.

To support inherent anticipation of the claimed methods by Kolterman ('220), the Examiner relies on the statement in the specification that obesity is a characteristic of "most

patients with Type II diabetes mellitus" and the statement in Tsanev that "up to 90% of diabetic patients are intrinsically obese." Final Office Action, page 28. Applicants respectfully point out that "most patients" and "up to 90% of diabetic patients" do not show that all patients with type II diabetes are obese. In fact, these statements indicate that not all patients with type II diabetes are obese and, thus, do not support inherent anticipation by Kolterman ('220).

Accordingly, a reference which teaches treating type II diabetic patients with an amylin or amylin agonist does not necessarily teach treating patient with obesity. Thus, the claimed invention cannot be recognized by one skilled in the art as inherently taught in the cited reference.

Applicants respectfully submit that Kolterman ('220) does not explicitly or inherently teach the claimed methods. Thus, the cited reference does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).[2]

In sum, Applicants respectfully submit that the cited references do not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102.

[2] Applicants note that since the pending claims are entitled to the priority of the filing date of the priority application, June 6, 1997, Kolterman ('220) is citable under 35 U.S.C. §102(a) rather than 35 U.S.C. §102(b). In any event, the claimed invention is not anticipated by the reference since Kolterman ('220) does not explicitly or inherently teach the claimed methods, as presented herein.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicants' Deposit Account No. 010535 referencing Docket No. 235/013US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: November 30, 2006

Respectfully submitted,

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